

REMARKS

By this amendment, claims 41 and 44-49 are canceled. New claims 50-55 are added. Thus, after this amendment, claims 40, 42-43, and 50-55 are pending in the application.

Reconsideration of the application, as amended, is respectfully requested.

Specification Objections

2. The specification has been amended to be double spaced. A clean copy of the amended specification is enclosed for entry in the application. The undersigned does not possess a true copy of the specification as filed. Thus, although it is believed that the above-appearing specification is a marked-up version of the specification as filed, there may be some inconsistencies that are unknown to the undersigned.

3. One world wide web address has been removed from the specification and has been replaced with a citation to a published reference. The other address was not necessary and has been deleted.

Claim Objections

4. Claim 43 has been amended by removing "kDA" and replacing it with "kDa."

5. Claim 47 has been canceled.

Drawings

6. A clean set of drawings has been provided.

Claim Rejections – 35 USC § 112

7. The specification has been amended to more clearly define the variants that are encompassed in the instant claims.

Polyclonal antibodies raised against *P. salmonis* were used to screen an expression library. Out of the 18 clones that were identified, 16 were for the full length OspA gene and two were for truncated OspA genes. No other genes were identified in the screening. Accordingly, the present application teaches a method to identify clones having the OspA epitopes of the claimed invention. Applicants respectfully submits that there was, at the time of filing, methodology to permit screening of variants having substitutions, deletions and/or insertions, and further, it would not take undue experimentation to generate the variants and then screen the variants.

The statement “the desired capability of OspA to act as an antigen and hence as a vaccine” has been replaced with the more specific statement: “the desired capability to elicit an immune response against *P. rickettsia* and hence to function effectively as a vaccine against same”.

8. Applicants submit that the amendments made to the specification in response to the written description objection additionally address the enablement rejection.

9. Applicants submit that the claims, as amended, particularly point out and distinctly claim the subject matter.

Claim 40 is amended to change “Nos 1, 3 or 5” to read “NO 1, 3, 5 and sequences having similarity to SEQ ID NO 1, 3 and 5 that do not alter one of the immunogenicity and function of said protein”.

Claim 41 is cancelled. New claim 50 reads as follows:

50. A protein of 16 kDa as determined by SDS PAGE comprised of the amino acid sequence of one of SEQ ID NO 2, 4, 6 and variants of SEQ ID NO 2, 4 and 6 that do not alter one of the immunogenicity and function of said protein.

Claim 42 is amended to change “approximately 17 kDa protein of claim 40, encompassing amino acid substitutions, additions or deletions that do not alter one of the immunogenicity and function of said protein” to read “protein of claim 40, wherein said protein is encoded by one of SEQ ID NO 1, 3 and 5”.

Claim 43 is amended to change “protein of approximately 17 kDa” to read “protein ranging from 15.5 to 17.7 kDa as determined by SDS PAGE, encompassing amino acid substitutions, additions or deletions that do not alter one of the immunogenicity and function of said protein”

Claim 44 is cancelled. New claim 51 reads as follows:

51. The protein of claim 50 wherein the amino acid sequence is selected from one of SEQ ID NO 2, 4 and 6.

Claims 45-46 are cancelled. New claims 52 and 54 are added. Applicants respectfully submits that the terminology “post-translationally modified into a lipoprotein” is clear to one skilled in the art.

Claims 47-49 are cancelled. New claims 53 and 55 are added.

Claim Rejections – 35 USC § 102

10. The applicants respectfully traverse the objection of anticipation re Anderson et al.

Anderson et al. teach that there is a 17kD protein that is conserved within the four Rickettsia species studied. This endogenous protein is the mature form of the protein and therefore has had the signal sequence for lipidation removed. The mature, endogenous protein of the instant invention, however, is not 17 kD, but rather is approximately 16 kD (Figure 1) as determined by SDS PAGE, and is approximately 15.5 kD as deduced from the gene sequence. Note that the data presented in the application as filed shows that the protein ranges in weight from 15.5 to

17.7 kDa depending upon the method of determination of the molecular weight (sequence analysis or SDS-PAGE) and whether the protein has the signal sequence or has been post translationally modified into the mature lipoprotein. Hence, applicant submits that no new matter has been introduced. The mature protein has the signal peptide removed and is lipidated. The approximately 17 kDa product in the instant invention is the expression product from the cloned gene that is approximately 17 kDa. The specification has been amended to more clearly describe the protein of the instant invention. Further evidence that these are not the same proteins can be gleaned from the sequence comparison. There is only 41% identity and 62% similarity between the amino acid sequences (Figure 2C).

Further to the above, although the Examiner contends that it would be inherent in the teachings of the prior art that the 17 kDa antigens would be cross reactive with the anti-*P. salmonis* since Anderson et al. teach that the 17kDa antigen is commonly conserved, in fact Anderson correctly teaches only that the gene, and not the protein is conserved, and further, that the gene is highly conserved within the spotted fever group (*R. rickettsia* and *R. conorii*) and similarly within the typhus group of rickettsia (*R. typhi* and *R. prowazekii*) but is less highly conserved between the two groups.

Of greatest significance is the fact that Anderson et al. teach that the majority of the amino acid substitutions occur in neutral or hydrophobic regions of the protein. These, Anderson et al. suggest, may be determinants found on the exterior portion of the antigen and may be surface exposed epitopes that have undergone antigenic variation. Hence, Anderson et al. teach away from the present invention.

The application is now in condition for allowance, and an action to that end is requested.

Respectfully submitted,

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